

Remarks

Applicants have canceled claims 1, 15, 17-19 and 22-25 without prejudice or disclaimer. Claims 27, 29-30, 37-38, 45-46, and 53-54 have been amended. New claims 60-96 have been added in order to claim additional embodiments of the subject matter of the invention. Support for amended claims 27, 29-30, 37-38, 45-46, 53-54 and 92 can be found throughout the specification as filed, for example, in paragraphs 68-69 and 148. Support for new claims 60-68 and 93 can be found, for example, in paragraphs 11, 70-71 and 130 of the specification. Support for new claims 69-73 and 94 can be found, for example, in paragraphs 73 and 148 of the specification. Support for new claims 74-86 and 95 can be found, for example, in paragraphs 76 and 149 and in Table 1 on pages 13-14 of the specification. Support for new claims 87-91 and 96 can be found, for example, in paragraphs 78 and 150 and in Table 2 on pages 15-16 of the specification. Additional support for all pending claims can be found in paragraph 91 of the specification. Thus, no new matter has been added.

Claims 27-30, 36-38, 44-46, 52-54 and 60-96 are pending.

I. Rejection Under 35 U.S.C. §112, First Paragraph

A. Claims 33, 41, 49, and 57

Claims 33, 41, 49 and 57 are rejected for allegedly containing new matter. Specifically, the Examiner states on page 3 of Paper No.6:

The specification as originally filed does not disclose nor suggest that administration of HMF can promote removal of malignant cells, as recited in the newly submitted claims. Also, the original claims do not recite that the administration of HMF to a patient promotes removal of malignant cells.

Applicants respectfully disagree and traverse.

Applicants note that claims 33, 41, 49 and 57 have been canceled. However, new claims 60-68 relate to the removal of malignant cells, so Applicants address this rejection as it may be applied to these new claims. Contrary to the Examiner's suggest, the specification clearly discloses that HMF can be used for therapeutic purposes including to remove malignant cells. For example, paragraph 11 on page 2 states that, "In accordance

with yet a further aspect of the present, there is provided a process for utilizing such polypeptides, or polynucleotide encoding such polypeptide, for therapeutic purposes, for example... to remove malignant cells.” Additionally, it is stated on page 12, paragraph 70 that, “The polypeptide of the present invention acts to stimulate differentiation of immature malignant leukemia cells thereby removing the immature malignant cell population.” Likewise, in paragraph 71 (including the two tables) it is further explained that HMF can elicit this same effect by inhibiting growth of cancer cells, as described in paragraph 130 (Example 2) of the specification. Thus, there is ample support in the specification for the phrase “removal of malignant cells.”

In view of the above statements, it is respectfully requested that this rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. Claims 27 and 44-59

The Examiner has rejected all claims that recite ATCC deposit No. 75514 as allegedly lacking enablement in the specification as originally filed. Specifically, the Examiner states on page 4 of the Paper No. 6:

The invention appears to employ novel biological materials, specifically ATCC deposit 75514... The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials, but there is no indication in the specification that the biological materials will be *irrevocably and without restriction or condition released to the public* upon the issuance of a patent.

In response, Applicants’ representative hereby gives the following assurance by signature below:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on August 4, 1993, accepted by the ATCC, and given ATCC

Accession Number ATCC 75514. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number ATCC 75514 were irrevocably removed due to the issuance of U.S. Patent 5,986,069, to which the instant application claims priority.

In light of the above, Applicants submit that the instant rejection under 35 U.S.C. § 112, first paragraph has been obviated. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

C. Claims 27-32, 34-40, 42, and 43

Claims 27-32, 34-40, 42, and 43 have been rejected for alleged lack of enablement in the specification. Applicants respectfully disagree and maintain that the above listed claims were fully enabled. However, claims 31, 32, 34, 35, 39, 40, 42 and 43 have been canceled, obviating the rejection of those claims. Claim 27 has been amended to claim a method for stimulating the proliferation and differentiation of hematopoietic progenitor cells, which is enabled by the specification as acknowledged by the Examiner (*see* page 5, second paragraph of Paper No. 6). Claims 29-30, 37-38, 45-46, and 53-54 have been amended to encompass administering the polypeptide of the invention to a patient suffering from leukemia or blood-related disorders, as disclosed in paragraph 69 of the specification and as further supported in paragraph 91.

New claims 60-91 have been added to encompass a method for removing malignant cells (as described in paragraphs 70-71 of the specification), a method for stimulating the proliferation of stromal cells (as disclosed in paragraph 73 of the specification), a method for stimulating the proliferation and differentiation of T-cells (as disclosed in paragraphs 76 and 149 of the specification), and a method for stimulating the proliferation of thymocytes (as disclosed in paragraphs 78 and 150). Applicants note that, as acknowledged by the Examiner on page 5 of Paper No.6, the specification is enabling for (i) a method for stimulating stromal cell proliferation, (ii) a method for stimulating the proliferation and differentiation of T-cells, and (iii) a method for stimulating the proliferation of thymocytes. Further, the specification is enabling for a method for removing malignant cells, optionally when administered to a patient with leukemia. Disclosure of these activities can be found in paragraphs 11, 70-71, 91 and 130 of the

specification as filed.

Thus, Applicants assert that the pending claims are fully enabled by the specification as filed, and therefore respectfully request that the rejection of claims 27-30 and 36-38 be reconsidered and withdrawn.

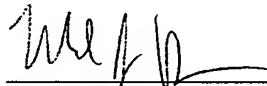
Conclusion

Entry of the above amendment is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the issuance of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

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